

Reasons for Allowance

The following is an Examiner's Statement of Reasons for Allowance: The prior art neither teaches nor fairly suggests the claimed modified HIV-1 gp41 polypeptides. The closest available prior art (Lu et al., 1999; previously cited by applicants)¹ discloses the preparation of a small modified gp41 polypeptide designated N34(L6)C28. This polypeptide consists of aa 546-579 (N34), a small linker (SGGRGG), and aa 628-655 (C-28) of gp41. It was reported that the inclusion of additional regions (e.g., N36) produced insoluble aggregates (see bridging paragraph, pp. 4434-4435). Accordingly, one of ordinary skill in the art would not have been motivated to include portions outside of N34 and C28. The polypeptides of the instant invention were obtained from a region of gp41 corresponding to amino acids 540-679, and encompass portions much larger than those disclosed by Lu et al. (1999). The polypeptides were modified by deleting an intervening loop between the N- and C-helices of gp41 (~593-617) and replacing it with a hydrophilic linker (SGGRGGS). This linker maintains the native configuration between the two helices and provides a soluble and stable trimeric form of the polypeptide. Additional modifications include amino- or carboxy-terminal truncations. Surprisingly, these polypeptides were soluble and stable. Accordingly, the claims are unobvious in view of the prior art. The amended claims accurately define the applicants' invention and are of such scope that the specification provides an enabling disclosure. Any comments considered necessary by applicant must be submitted no later

than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Zachariah Lucas, can be reached at (571) 272-0905. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

¹ Lu, M., et al., 1999, Subdomain folding and biological activity of the core structure from human immunodeficiency virus type 1 gp41: implications for viral membrane fusion, J. Virol. 73(5):4433-4438.

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Applicants: Fleury, S., et al.

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Respectfully,

/Jeffrey S. Parkin/
Primary Examiner, Art Unit 1648

01 November, 2010